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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/133,813 08/13/98 NODA

W CA-5740-NP

EXAMINER

QM32/0217

BIANCO, P

ART UNIT

PAPER NUMBER

3762

DATE MAILED:

02/17/00

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/133,813

Applicant(s)  
Noda et al.

Examiner  
Patricia Blanco

Group Art Unit  
3762



☒ Responsive to communication(s) filed on Sep 3, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-63 is/are pending in the application.

Of the above, claim(s) 11, 12, and 14-63 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-3, 5-7, 9, 10, and 13 is/are rejected.

☒ Claim(s) 4 and 8 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2, 3, 4, 8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election without traverse of Group I and Species F (Figs. 20-24) in Paper No. 7 is acknowledged. Claims 1-10 & 13 have been examined at this time.

Claims 11, 12 & 14-63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention and species. Election was made **without** traverse in Paper No. 7. Claims 12, 28-37, 39, 52-55, & 61-63 were elected by Applicant, however, the claims do not read on the elected species. Claims 28-37, 39, & 61-63 require a second manifold which is not a limitation of the claimed species and claims 52-55 require a coating which reads on species C.

### ***Oath/Declaration***

It was not executed in accordance with either 37 CFR 1.66 or 1.68. The declaration is missing two signatures.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-10 & 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 it is stated that the fibers provide fluid communication between the first and second fluid flow paths but it is unclear how this is done since the fibers are not structurally connected to either flow path.

In claim 3 it is stated that the inner tube "has properties for moving relative to the outer tube" for varying configuration of the hollow fibers between the inner and outer tube. The limitation "properties" is not clearly claimed or explained to understand what "moving relative" entails.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7, 9, 10 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berry et al. (4,850,958) in view of Saab (5,624,392).

Berry et al. teaches of a device for use in the venous system for allowing blood gas exchange by passing oxygen rich gas through an elongated tubular member (10) comprising an

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inner lumen (26) gas permeable tubes (12) attached to the proximal and distal ends. The gas permeable tubes expand upon oxygenation (see fig. 3, col. 8, lines 3-10). The tubes have a distal (16) and proximal (14) end which are attached to the main tubular member at chambers (28) and (30). These chambers provide a means for enclosing the tubes on the main tubular member while further providing an airtight seal at each end. The chambers further comprise a potting agent to produce the airtight bond between the gas permeable tubes and a spacer lumen (32) which is along the inner lumen (26) member. (See col. 4, line 64-col. 6, line 6; figs. 1-4).

Berry et al. does not teach of two tubes having distinctly spaced apart lumens to allow for circulation of heat exchange fluid through the entire device.

Saab teaches of a heat transfer catheter (230) comprising an inner catheter tube (234) defining a lumen therethrough surrounded by an outer tube (232) and defining a lumen therethrough. The catheter also has an expandable balloon portion (236) with tapered ends (238, 240) to attach it to the outer member. Heat transfer fluid enters the inner lumen and exits through the outer lumen thereby dilating the balloon and transferring heat to the blood in the vessel said catheter resides within. (Col. 13, lines 21-46; figures 4-6).

At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the catheter of Berry et al. to include a second lumen (outer lumen) around the inner tubular lumen to allow the oxygenated gas to move out of the tubular members and recirculate through the device and allow the temperature of the surrounding blood to increase.

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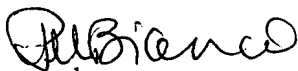
***Allowable Subject Matter***

Claims 4 & 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

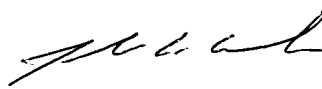
***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nichols teaches of an analogous method of delivering heat to the body and Schreiner teaches of an analogous catheter device having a wire delivery member disposed on its catheter shaft.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Bianco whose telephone number is (703) 305-1482.

  
pmb

January 17, 2000

  
John G. Weiss  
Supervisory Patent Examiner  
Group 3700